Sheffield Laboratories, Div. Faria Ltd

World's First Toothpaste

Manufacturer, Est. 1850

AUG 2 2000

K001077

510(k) Summary

Applicant:

Sheffield Laboratories, Div. of Faria Ltd.

170 Broad Street

New London, CT 06320 USA

Phone:

(860) 442-4451

Fax:

(860) 442-0356

Contact:

Kathleen Hacku

Date:

March 27, 2000

Device:

Trade Name:

Lubrigel Personal Lubricant

Common name:

Personal Lubricant

• Classification name:

Lubricant, Patient (per 21 CFR section 880.6375)

Information supporting claims of substantial equivalence, as defined under the Federal Food Drug and Cosmetic Act, with respect to safety and effectiveness is summarized below. For the convenience of the reviewer, this summary is formatted in accordance with the Agency's final rule, "510(k) Summaries and 510(k) Statements" (21CFR807).

New Device's Name:

Sheffields's LubriGel Personal Lubricant

Predicated Devices(s):

K-Y Jelly Personel Lubricant, Ortho-McNeil

Pharmaceuticals, Inc., K955648

ASTROGLIDE Personal Lubricant, BioFilm Inc., K935291

Intended Use:

"Sheffield's *LubriGel* Personal Lubricant" is an over-the-counter personal lubricant, specially formulated to lubricate condoms, provide vaginal moisture, and ease the insertion of rectal thermometers, enemas, douches and tampons.

Device Description:

LubriGel Personal Lubricant formula is clear, colorless, odorless, non-sticky, non-greasy, non-irritating personal lubricant. It is a water soluble clear, high viscosity gel-like liquid. Because it is water-soluble, LubriGel

K001077

is easily rinsed off with water. The product is packaged in a convenient laminate tube with a flip top cap.

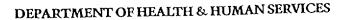
Technological Characteristics:

LubriGel contains only United States Pharmacopeia (USP) or National Formulary (NF) of: Carboxymethy Cellulose, Citric Acid, Methylparaben, Natural Glycerin, Propylparaben and Purified Water.

Summary of Technological Characteristics:

The table below compares the technological characteristics of Sheffield's *LubriGel* to the predicated devices K-Y Brand Liquid Personal Lubricant and ASTROGLIDE.

Feature	LubiGel	K-Y Jelly	ASTROGLIDE
Manufacture	Sheffield	Ortho-McNeil	BioFilm, Inc
	Laboratories, Div.	Pharmaceutical,	
	Faria Ltd.	Inc.,	
Contains purified	yes	yes	yes
water			
Contains glycerine	yes	yes	yes
Contains Cellulose	yes	yes	no
thickeners			
Contains	yes	yes	yes
Methylparaben			703
Contains	yes	no	yes
Propylparaben			703
Labeled Water	yes	yes	yes
soluble			703
Labeled Non-	yes	yes	yes
staining			703
Labeled Condom	yes	yes	yes
compatible		1	yes
Labeled Alcohol	yes	yes	no
and Fragrance Free			
Container Material	Plastic	Plastic	Plastic
Sterile	No	No	No





AUG 2 2000

Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

Ms. Kathleen Hacku Quality Assurance Manager Sheffield Laboratories, Div. Faira Ltd. 170 Broad St. New London, CT. 06320 Re: K001077

Lubrigel Personal Lubricant Dated: July 18, 2000 Received: July 24, 2000 Regulatory Class: II

21CFR 884.5300/Procode: 85 HIS 21CFR 880.6375/Procode: 85 MMS

Dear Ms. Hacku:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act Include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours

Daniel G. Schultz, M.D.

Captain, USPHS

Director, Division of Reproductive, Abdominal, and Radiological Devices

Office of Device Evaluation Center for Devices and Radiological Health

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Page 3_ of ___

510(k) Number (if known): _K001077

Device Name: Sheffield's LubriGel Personal Lubricant

Indications for Use:

LUBRIGEL is specially formulated to lubricate condoms, provide vaginal moisture, and ease the insertion of rectal thermometers, enemas, douches and tampons.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurence of CDRH, Office of Device Evaulation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,

and Radiological Devices

510(k) Number 5001077

http://www.fda.gov/cdrh/ode/indicate.html

7/28/00

use: Over the count